K112373

INNOVA VISION, INC.
No.231-1, Wen-Te Road, Chiung-Lin Village,
Hsin-Chu County,307, Taiwan, R.O.C.
TEL：886-3-5927299 FAX：886-3-5926213

510 (K) Summary

AUG 17 2012

SUMMARY OF SAFETY AND EFFECTIVENESS FOR
Calaview Color (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear

Submitter Information:

Company:	INNOVA VISION INC.
	No. 231-1, Wen-Te Road, Chiung-lin Village, Hsin-Chu County, Taiwan.
Contact Person:	Mr. Michael w. Hsu,
	Executive Vice President
Phone:	886-3-592-7299
FAX:	886-3-592-6213
E-Mail:	mikehsu@innovavision.com.tw
Date Prepared	July 4, 2011

Identification of Device:

Classification Name:	Soft hydrophilic contact lens, per 21 CFR. 886.5925
Trade Name:	Calaview Color (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Common or usual Name:	Soft (hydrophilic) Contact lens (daily wear)
FDA Classification:	Class II

Predicate Device:

Calaview (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear cleared via K073060 from INNOVA VISION INC.

Indications for Use

Calaview Color (Etafilcon A) Soft (hydrophilic) Contact Lens is indicated for **daily wear** for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic and may exhibit refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity.'

Eye care practitioners may prescribe the lenses for either single-use daily disposable wear or frequent/planned replacement wear with cleaning, rinsing, disinfection and scheduled replacement **as prescribed by the eye care professional**. When prescribed for frequent/planned replacement wear , The contact lens may be disinfected using chemical (not heat) disinfection system.

Description of Device

Calaview Color (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is available as aspherical lenses manufactured by spin-casting method. The model illuminated with high water content (58 %).

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The hydrogel lens' material is a random copolymer composed of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA), which was cross-linked with 1,1,1-trimethylolpropane trimethacrylate (TMPTMA) and Ethylene Glycol Dimethacrylate (EGDMA) via UV photo- polymerization. The Calaview Color (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear contains pigments around the non-optic area that will mask or enhance the color of the natural iris without blocking the light transmittance. The lens is colored with one or more of the FDA-approval color additives: iron oxides, titanium dioxide, phthalocyaninato copper, phtalocyanine green, vat orange 1. The Calaview Color (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is available in the following opaque colors: Blue, green, violet, gray, hazel, white, yellow, gold, orange red and black. Lenses are supplied sterile in sealed glass vials containing sterile isotonic phosphate buffered saline solution.

Summary of Clinical Study

This special 510(k) application describes a labeling modification to the predicate device -- Calaview (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear cleared via K073060 INNOVA VISION INC.. There is no change in lens material, the manufacturing process, nor the parameter and properties. The difference between predicate and subject device is packaging vehicles. Namely, the predicate device is pp blister packaging and that of subject device is glass vials. Therefore, the clinical data previously submitted in K073060 supports the clinical safety of the subject device.

Nonclinical Studies

All testing was conducted in accordance with the May 1994 FDA guideline titled *Premarket Notification 510(K) Guidance Document for Class IV Contact lenses,* and in conformance to applicable device regulations.

This special 510(k) application describes a labeling modification to the predicate device -- Calaview (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear cleared via K073060. There is no change in lens material, the manufacturing process, nor the parameter and properties. Therefore, the non-clinical data previously submitted in K073060 supports the clinical safety of the subject device. The non-clinical performance tests had been performed to demonstrate the safety and effectiveness of the Calaview Color (Etafilcon A) Soft (hydrophilic) Contact Lens, and establish substantial equivalence to predicate lenses-Calaview (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear cleared via K073060. The evidence of substantial equivalent to the predicate lens described as follow:

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a) Technological characteristics studies

There characterizations of Calaview Color (Etafilcon A) Soft (hydrophilic) Contact Lens are equivalent and comparable to those of predicate lenses.

Characteristic	Predicate Device Calaview	Subject Device Calaview Color
%Water content	57 to 59	57 to 59
Refractive index	1.407	1.407
Specific Gravity	1.05	1.05
Oxygen permeability (edged corrected) @ 35℃	24×10^{-11} [(cm2/sec)(ml O2/ml-mmHg)]	24×10^{-11} [(cm2/sec)(ml O2/ml-mmHg)]
%Light Transmission	>93	>93
Base Curve Radius, mm	8.00~9.00	8.00~9.00
Diameter, mm	13.8~14.2	13.8~14.2
Center Thickness @-3.0D, mm	0.08~0.12	0.08~0.12
Power, Diopters	+6.0D~-12.0D	+6.0D~-12.0D

b) Biocompatibility

In accordance with the May 1994 Guidance Document for daily wear contact lenses, toxicity studies have been conducted on the predicate model: Calaview (Etafilcon A) Soft (hydrophilic) Contact Lens. The Irritation test in the rabbit eye and Systemic toxicity studies indicate the extracts would be considered as non-toxic and nor irritated. The Cytotoxicity testing demonstrates the lens is not cytotoxic under the conditions of the study. There is no change in lens material, the manufacturing process, nor the parameter and properties between subject device and that of predicate lens. Therefore, there are no biocompatibility risks for subject device-I: Calaview Color (Etafilcon A) Soft (hydrophilic) Contact Lens.

c) Microbiology

Steam sterilization process has been validated to deliver a minimum SAL of 10^{-6}, thereby complying with the requirement of FDA Group IV. There is shelf-life stability data supporting that the lens remains sterile through the expiration date claimed for the product.

d) Leachability

Studies were conducted to determine the leachable materials from the finished lens. The results show that, at the levels of the detection reported, there are no leachable monomers and addictive residues.

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Substantial equivalence Statement

Testing performed on the Calaview Color Soft (hydrophilic) Contact Lens for Daily Wear indicated that it can support the safety and effectiveness as well as the predicate devices- Calaview (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (K073060), when used in accordance with the instructions for use. Moreover, the Calaview Color (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear has identical lens material, manufacturing process, parameters and properties as ,the predicate device -- Calaview (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear cleared via K073060 INNOVA VISION INC..

In conclusion, it is Innova's conviction that data submitted in this 510(k) to validate the claim of substantial equivalency, substantiates our ability to manufacture a soft contact lens, the Calaview Color Soft (hydrophilic) Contact Lens, with the same established safety profile and effectiveness as the predicate device-- Calaview (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (K073060).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Innova Vision, Inc.
c/o Ms. Jennifer Reich
Harvest Consulting Corp.
2904 N. Boldt Drive
Flagstaff, AZ 86001

AUG 17 2012

Re: K112373
Trade Name: Calaview (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulatory Class: II
Product Code: LPL
Dated: July 9, 2012
Received: July 19, 2012

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number: **K112373**

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Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devices

510(k) Number K 112373

Prescription Use: ☑ or Over the Counter Use: ☐